

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

A Comparative study of the preoperative effects of Rosemary gargle versus Lidocaine gargle on sore throat and voice violence after endotracheal intubation under general anesthesia in candidates patients for surgeries

Protocol summary

Study aim

We want to assess the effect of Rosemary gargle versus Lidocaine gargle to find a prophylactic treatment that has high effect on sore throat and voice violence after intubation and also has less side effect

Design

Randomized, triple blind clinical trial with 1 control group and 2 intervention groups and phase 3 study of 90 patients. We use Random allocation app to randomize the study.

Settings and conduct

Before intubation and preemptively, in group1 we will give gargle of 30 drops of Rosemary solution 5% (Aboureihan company) which will be diluted with 30 drops of distilled water with surgical mesh 2-3 minutes before general anesthesia, In group2 we will give gargle of Lidocaine solution 2% (with dose of 1mg/kg) which will be diluted with 30 drops of distilled water with surgical mesh 2-3 minutes before general anesthesia. In group3 we will give gargle of 30 drops of distilled water with surgical mesh 2-3 minutes before general anesthesia. Research place : Hospitals of Isfahan university of medical sciences (Alzahra and Kashani hospitals).

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate patients for surgery; ASA 1,2; age between 18 to 65 years old; informed consent of patient. Non -inclusion criteria: IV or opioid addicts; previous allergy to this research,s drugs; Heart, Renal or Hepatic failure patients; hard intubation (Grade 4 or upper); malformation of airway tract.

Intervention groups

We have 3 intervention groups. In group 1 we will administer Rosemary gargle; group 2 Lidocaine gragle and group 3: distilled water gargle.

Main outcome variables

Voice violence; sore throat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005362N29**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences, Isfahan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
A Comparative study of the preoperative effects of Rosemary gargle versus Lidocaine gargle on sore throat and voice violence after endotracheal intubation under general anesthesia in candidates patients for surgeries

Public title
Comparison between Rosemary gargle versus Lidocaine gargle on sore throat and voice violence after endotracheal intubation under general anesthesia in candidates patients for surgeries

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patient for surgery ASA 1,2 Age between 18 to 65 years old Informed consent of patient

Exclusion criteria:
IV or Opioid drugs addicts Previous Allergy to drugs (Rosemary,Lidocaine) Patients with Heart,Renal pr Hepatic failure Hard Intubation (Grade 4 or upper) Malformation of airway tract

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyster

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling method will be simple random allocation. Simple random allocation is the easiest and most basic approach that provides unpredictability of treatment assignment. In simple random allocation, treatment assignment is made by chance without regard to prior allocation. For randomization we enter all of samples that have entrance criteria and also not have non-entrance criteria until the volume of samples will be completed. Then we will use the app to randomize them into 3 groups completely randomized. Unit of randomization is group of persons. The tool of randomization will be Random allocation App.That will make sequences based on special programming.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this research patients, intervention physician and data analyzer do not have any information about groups and using drugs and also their own method. Data will be

analyzed without notice to any of persons above. Only the main performer has information bout groups and each one using drugs.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib street, Azadi square

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-11-04, 1400/08/13

Ethics committee reference number

IR.MUI.MED.REC.1400.621

Health conditions studied

1

Description of health condition studied

Sore throat

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

2

Description of health condition studied

Hoarseness

ICD-10 code

R49

ICD-10 code description

Voice and resonance disorders

Primary outcomes

1

Description

Intensity of sore throat based on VAS scale

Timepoint

Every 15 minutes at recovery, every 2 hours in first 6

hour and then at 12 and 24 hours after operation

Method of measurement

Visual Analogue Scale

2

Description

Intensity of voice violence

Timepoint

Every 15 minutes at recovery, every 2 hours in first 6 hour and then at 12 and 24 hours after operation

Method of measurement

Grade, Roughness, Breathiness, Asthenia, Strain Scale (voice disorder assessment)

Secondary outcomes

1

Description

Average satisfaction level of patients

Timepoint

First 48 hours after operation

Method of measurement

Hours count that will be measured by researcher.

2

Description

Average of first time liquids regime toleration

Timepoint

First 48 hours after operation

Method of measurement

Hours count that will be measured by researcher.

3

Description

Average of first time solids regime toleration

Timepoint

First 48 hours after operation

Method of measurement

Hours count that will be measured by researcher.

Intervention groups

1

Description

Intervention group: In group1 we will give gargle of 30 drops of Rosemary solution 5% (Aboureihan company) which will be diluted with 30 drops of distilled water 2-3 minutes before general anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group: In group2 we will give gargle of Lidocaine solution 2% (with dose of 1mg/kg) which will be diluted with 30 drops of distilled water 2-3 minutes

before general anesthesia.

Category

Treatment - Drugs

3

Description

Control group: In this group we will give gargle of 30 drops of distilled water 2-3 minutes with surgical mesh before general anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr. Mohammadreza Safavi Homami

Street address

Soffe blvd., Kharrazi highway

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2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

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Street address

Kharrazi highway, Beheshti blvd, Kashani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mansoor Siavash Dastjerdi

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research@mui.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Safavi Homami

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available